

Notice of Allowability

Application No.

10/800,024

Examiner

Suzanne M. Noakes, Ph.D.

Applicant(s)

AERTGEERTS ET AL

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicants amendments filed 3/13/07 and the phone interview 3/23/ and 3/26/07.
2. ☒ The allowed claim(s) is/are 1,4,25,28,32,49,55,79 and 80.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>20070326</u> |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Robin Silva on 26 March 2007.

The application has been amended as follows:

In the claims:

- Amend claim 1: A composition comprising a protein in crystalline form wherein the protein consists of ~~amino acids 24-292 of SEQ ID No: 1~~ SEQ ID No: 5 and wherein the protein crystal has a crystal lattice in a $P2_1$ space group and unit cell dimensions, +/- 5% of $a=56.4 \text{ \AA}$, $b=152.5 \text{ \AA}$, $c=73.8 \text{ \AA}$, $\alpha=90^\circ$, $\beta=92.2^\circ$ and $\gamma=90^\circ$.
- Amend claim 25: A method for forming a crystal of a protein comprising:
forming a crystallization volume comprising a precipitant solution and a protein that consists of ~~amino acids 24-292 of SEQ ID No: 1~~ SEQ ID No: 5 and wherein the protein crystal has a crystal lattice in a $P2_1$ space group and unit cell dimensions, +/- 5% of $a=56.4 \text{ \AA}$, $b=152.5 \text{ \AA}$, $c=73.8 \text{ \AA}$, $\alpha=90^\circ$, $\beta=92.2^\circ$ and $\gamma=90^\circ$; and storing the crystallization volume under conditions suitable for crystal formation of the protein.

- Amend claim 49. A soluble protein consisting of ~~amino acids 24-292 of SEQ ID No: 1~~ SEQ ID No: 5.
- Cancel claim 50.
- Amend claim 55. A non-crystalline protein consisting of SEQ ID No: 5.
- Cancel claims 9, 12, 17, 20, 33, 36, 40, 41, 44, 48, 51-54, 56-58, 61-65, 68-72 and 75-78.
- Add claim 79. An isolated soluble protein consisting of SEQ ID No: 5.
- Add claim 80. An isolated non-crystalline protein consisting of SEQ ID No: 5.

Reasons for Allowance

2. The following is an examiner's statement of reasons for allowance: The claims are drawn to a crystal of 11- β -Hydroxysteroid dehydrogenase Type 1 and soluble and non-crystalline proteins thereof consisting of SEQ ID No: 5. Said sequence is amino acids 24-292 of wild-type 11- β -Hydroxysteroid dehydrogenase that includes a 17 amino acid His-tag at the N-terminus and a Cys to Ser substitution at residue 272 as compared to the wild-type (e.g. SEQ ID No: 1). No 11- β -Hydroxysteroid dehydrogenase from any source has been crystallized previously; furthermore, a careful search of SEQ ID No: 5 against other amino acid databases, both commercial and interference databases, revealed that no prior art exists. The inclusion of soluble and non-crystalline in claims 49 and 55, while not supported verbatim in the specification, is believed not to introduce new matter since clearly the specification describes soluble SEQ ID No: 5 which is in a

non-crystalline form. Thus **claims 1, 4, 25, 28, 32, 49, 55, 79 and 80** are in condition for Allowance.

Reference of Interest – Not Relied Upon

3. Stulnig et al. (Diabetologia, 2004 , 47 :1-11) teaches the current role that 11- β -hydroxysteroid dehydrogenase Type 1 has on obesity and Type II diabetes, and also suggests the possibility of novel therapeutic options might be viable through inhibition or down-regulation of said enzyme.

Conclusions

4. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 7.00am to 3.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SMN

26 March 2007



4-2-07
DAVID J. STEADMAN, PH.D.
PRIMARY EXAMINER